Congress of the United States Washington, DC 20515

February 17, 2021

The Honorable Xavier Becerra

Secretary

Dept. of Health and Human Services 200 Independence Avenue SW

Washington, DC 20201

Dr. Anthony Fauci, M.D.

Director

Ntl. Institute of Allergy and Infectious Diseases

5601 Fishers Lane Bethesda, MD 20892

Dr. Lawrence A. Tabak, D.D.S. Ph.D. Acting Director National Institutes of Health 9000 Rockville Pike Bethesda, MD 20892

Dear Secretary Becerra, Dr. Fauci, and Dr. Tabak,

We thank the scientific community for their efforts to find safe and effective treatments for COVID-19, and we urge you to rapidly proceed with developing and testing combination therapies toward that end.

As you know, decades of experience combatting HIV and other viruses have shown that combination therapy, or 'cocktails' of multiple therapeutics, is frequently the most effective way to combat viruses and prevent death. For example, during this pandemic, we have seen promising results from the monoclonal antibody cocktail when administered to COVID-19 patients via an intravenous infusion.

After many months of research throughout this pandemic, we currently have several medications that have shown significant effectiveness during clinical trials in preventing hospitalization and death when administered to early-stage COVID-19 patients. These include Merck's Lagevrio (molnupiravir)¹, Pfizer's Paxlovid (PF-07321332 and ritonavir)², the generic drug fluvoxamine³, and potentially others. Due to these drugs' widely differing mechanisms of action, many scientists believe it is plausible, or even likely, that these drugs could be synergistic in treating early COVID-19. If so, a cocktail of these and other medications could be our best tool to fight COVID-19 and its future variants.

However, the pharmaceutical companies that developed these drugs do not have a natural commercial incentive to formulate and test therapeutic cocktails. Similarly, generic drugs that are off patent do not have a natural advocate for inclusion into cocktails. Therefore, it is necessary

¹ Merck and Ridgeback Biotherapeutics Provide Update on Results from MOVe-OUT Study of Molnupiravir, an Investigational Oral Antiviral Medicine, in At Risk Adults With Mild-to-Moderate COVID-19

² Pfizer Seeks Emergency Use Authorization For Novel COVID-19 Oral Antiviral Candidate

³ Effect of early treatment with fluvoxamine on risk of emergency care and hospitalisation among patients with COVID-19: the TOGETHER randomised, platform clinical trial

for the federal government to aggressively step in and run – or at the very least, fund – these trials.

We understand that some arms of the NIH ACTIV trials are considering or have already undertaken this approach. However, determining the optimal combination of these and other drugs will require a very large, systematic trial testing numerous therapeutic combinations and dosages. Multiple iterations of the standard of care will be needed to converge on an optimal treatment for different patient populations. A large increase in the level of effort is indicated. Therefore, we urge you to take steps to accelerate the investigation into combination therapies, including:

- Speeding up recruitment and expanding the size and number of the ACTIV trials and other internal efforts, and further focus them on testing and optimizing combination
- Increasing support and facilitating developmental drug availability to existing adaptive platform trials, including international adaptive platform trials such as the TOGETHER Trial and others, that are attempting to investigate and develop combination therapy.

Finding the most effective treatments for COVID-19 is a top-tier public health priority as infections rage, variants spread, and more and more scientists expect the disease to become endemic. We are deeply appreciative of the work you have put toward developing treatments, including combination therapies, thus far. If there's anything we can do in Congress to help you advance our shared goals, please do not hesitate to let us know.

Sincerely,

Bill Foster Member of Congress

Bill Foster

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